

Updated Information | Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities (NDSRIs) | FDA

*Source is the form of the drug substance in the free base or free acid form.

NDSRI Name	Source*	Potency Category	Recommended AI Limit
N-nitroso-abacavir	Abacavir	5	1500 ng/day
N-nitroso-acarbose	Acarbose	5	1500 ng/day
N-nitroso-acebutolol	Acebutolol	4	1500 ng/day
N-nitroso-albuterol	Albuterol	5	1500 ng/day
N-nitroso-desmethyl-almotriptan	Almotriptan	1	26.5 ng/day
N-nitroso-desmethyl-amitriptyline	Amitriptyline	1	26.5 ng/day
N-nitroso-amlodipine	Amlodipine	5	1500 ng/day
N-nitroso-amoxapine	Amoxapine	3	400 ng/day
N-nitroso-argatroban	Argatroban	4	1500 ng/day
N-nitroso-articaïne	Articaïne	4	1500 ng/day
N-nitroso-atenolol	Atenolol	4	1500 ng/day
N-nitroso-atomoxetine	Atomoxetine	1	26.5 ng/day
N-nitroso-avanafil	Avanafil	3	400 ng/day
N-nitroso-desmethyl-bedaquiline	Bedaquiline	1	26.5 ng/day
N-nitroso-benazepril	Benazepril	5	1500 ng/day
N-nitroso-bendroflumethiazide	Bendroflumethiazide	5	1500 ng/day
N-nitroso-berotralstat	Berotralstat	2	100 ng/day
N-nitroso-betaxolol	Betaxolol	4	1500 ng/day
N-nitroso-bicisate	Bicisate	4	1500 ng/day
N-nitroso-bisoprolol	Bisoprolol	4	1500 ng/day
N-nitroso-brilliant blue g	Brilliant Blue G	5	1500 ng/day
N-nitroso-brinzolamide	Brinzolamide	2	100 ng/day
N-nitroso-desmethyl-brompheniramine	Brompheniramine	1	26.5 ng/day
N-nitroso-bumetanide	Bumetanide	4	1500 ng/day
N-nitroso-bupropion	Bupropion	5	1500 ng/day
N-nitroso-desmethyl-cabergoline	Cabergoline	1	26.5 ng/day
N-nitroso-cangrelor	Cangrelor	3	400 ng/day
N-nitroso-desmethyl-carbinoxamine	Carbinoxamine	1	26.5 ng/day
N-nitroso-carteolol	Carteolol	5	1500 ng/day
N-nitroso-carvedilol	Carvedilol	3	400 ng/day
N-nitroso-caspofungin	Caspofungin	4	1500 ng/day
N-nitroso-desmethyl-chlophedianol	Chlophedianol	1	26.5 ng/day
N-nitroso-chloroquine	Chloroquine	5	1500 ng/day
N-nitroso-desmethyl-chlorpheniramine	Chlorpheniramine	1	26.5 ng/day
N-nitroso-desmethyl-chlorpromazine	Chlorpromazine	1	26.5 ng/day
N-nitroso-cinacalcet	Cinacalcet	3	400 ng/day
N-nitroso-desmethyl-citalopram	Citalopram	1	26.5 ng/day
N-nitroso-desmethyl-clarithromycin	Clarithromycin	4	1500 ng/day
N-nitroso-clevidipine	Clevidipine	5	1500 ng/day
N-nitroso-desmethyl-clomipramine	Clomipramine	1	26.5 ng/day
N-nitroso-clozapine	Clozapine	5	1500 ng/day
N-nitroso-colistin a hydrogen methanesulfonate-1	Colistin	2	100 ng/day
N-nitroso-colistin a hydrogen methanesulfonate-2	Colistin	2	100 ng/day
N-nitroso-colistin a hydrogen methanesulfonate-3	Colistin	2	100 ng/day
N-nitroso-colistin a hydrogen methanesulfonate-4	Colistin	2	100 ng/day
N-nitroso-colistin a hydrogen methanesulfonate-5	Colistin	2	100 ng/day
N-nitroso-colistin b hydrogen methanesulfonate-1	Colistin	2	100 ng/day
N-nitroso-colistin b hydrogen methanesulfonate-2	Colistin	2	100 ng/day
N-nitroso-colistin b hydrogen methanesulfonate-3	Colistin	2	100 ng/day
N-nitroso-colistin b hydrogen methanesulfonate-4	Colistin	2	100 ng/day
N-nitroso-colistin b hydrogen methanesulfonate-5	Colistin	2	100 ng/day
N-nitroso-desmethyl-cyclobenzaprine	Cyclobenzaprine	1	26.5 ng/day
N-nitroso-dabigatran etexilate	Dabigatran Etexilate	3	400 ng/day
N-nitroso-degarelix	Degarelix	3	400 ng/day
N-nitroso-desmethyl-demeclocycline	Demeclocycline	3	400 ng/day
N-nitroso-desipramine	Desipramine	1	26.5 ng/day
N-nitroso-desloratadine	Desloratadine	3	400 ng/day
N-nitroso-desmethyl-desvenlafaxine	Desvenlafaxine	1	26.5 ng/day
N-nitroso-desmethyl-dexbrompheniramine	Dexbrompheniramine	1	26.5 ng/day
N-nitroso-desmethyl-dexchlorpheniramine	Dexchlorpheniramine	1	26.5 ng/day
N-nitroso-diclofenac	Diclofenac	5	1500 ng/day
N-nitroso-desmethyl-diltiazem	Diltiazem	1	26.5 ng/day
N-nitroso-desmethyl-diphenhydramine	Diphenhydramine	1	26.5 ng/day
N-nitroso-dipivefrin	Dipivefrin	2	100 ng/day
N-nitroso-dobutamine	Dobutamine	4	1500 ng/day
N-nitroso-dorzolamide	Dorzolamide	2	100 ng/day

N-nitroso-desmethyl-cidoxepin	Doxepin	1	26.5 ng/day
N-nitroso-desmethyl-doxepin, (e)-	Doxepin	1	26.5 ng/day
N-nitroso-desmethyl-doxycycline	Doxycycline	3	400 ng/day
N-nitroso-desmethyl-doxylamine	Doxylamine	1	26.5 ng/day
N-nitroso-duvelisib	Duvelisib	5	1500 ng/day
N-nitroso-elagolix	Elagolix	4	1500 ng/day
N-nitroso-enalapril	Enalapril	5	1500 ng/day
N-nitroso-enalaprilat	Enalaprilat	5	1500 ng/day
N-nitroso-ephedrine	Ephedrine	4	1500 ng/day
N-nitroso-epinephrine	Epinephrine	2	100 ng/day
N-nitroso-desmethyl-eravacycline	Eravacycline	3	400 ng/day
N-nitroso-ertapenem	Ertapenem	4	1500 ng/day
N-nitroso-desmethyl-erythromycin	Erythromycin	4	1500 ng/day
N-nitroso-desmethyl-erythromycin ethylsuccinate	Erythromycin Ethylsuccinate	3	400 ng/day
N-nitroso-desmethyl-escitalopram	Escitalopram	1	26.5 ng/day
N-nitroso-esketamine	Esketamine	5	1500 ng/day
N-nitroso-esmolol	Esmolol	4	1500 ng/day
N-nitroso-ethambutol	Ethambutol	4	1500 ng/day
N-nitroso-etravirine	Etravirine	5	1500 ng/day
N-nitroso-felodipine	Felodipine	5	1500 ng/day
N-nitroso-fenfluramine	Fenfluramine	3	400 ng/day
N-nitroso-fenoldopam	Fenoldopam	2	100 ng/day
N-nitroso-flecainide	Flecainide	4	1500 ng/day
N-nitroso-florbetaben f-18	Florbetaben F-18	2	100 ng/day
N-nitroso-florbetapir f-18	Florbetapir F-18	2	100 ng/day
N-nitroso-flutemetamol f-18	Flutemetamol F-18	2	100 ng/day
N-nitroso-folic acid	Folic Acid	4	1500 ng/day
N-nitroso-formoterol	Formoterol	4	1500 ng/day
N-nitroso-fosdenopterin-1	Fosdenopterin	5	1500 ng/day
N-nitroso-fosdenopterin-2	Fosdenopterin	5	1500 ng/day
N-nitroso-fostamatinib-1	Fostamatinib	5	1500 ng/day
N-nitroso-fostamatinib-2	Fostamatinib	5	1500 ng/day
N-nitroso-frovatriptan	Frovatriptan	3	400 ng/day
N-nitroso-furosemide	Furosemide	4	1500 ng/day
N-nitroso-gatifloxacin	Gatifloxacin	4	1500 ng/day
N-nitroso-hydroxychloroquine	Hydroxychloroquine	5	1500 ng/day
N-nitroso-imatinib	Imatinib	5	1500 ng/day
N-nitroso-isoproterenol	Isoproterenol	4	1500 ng/day
N-nitroso-isoxsuprine	Isoxsuprine	5	1500 ng/day
N-nitroso-isradipine	Isradipine	5	1500 ng/day
N-nitroso-ivacaftor	Ivacaftor	5	1500 ng/day
N-nitroso-ketamine	Ketamine	5	1500 ng/day
N-nitroso-labetalol	Labetalol	4	1500 ng/day
N-nitroso-leucovorin-1	Leucovorin	4	1500 ng/day
N-nitroso-leucovorin-2	Leucovorin	4	1500 ng/day
N-nitroso-levabuterol	Levalbuterol	5	1500 ng/day
N-nitroso-levamlodipine	Levamlodipine	5	1500 ng/day
N-nitroso-levmetamfetamine	Levmetamfetamine	3	400 ng/day
N-nitroso-levobunolol	Levobunolol	5	1500 ng/day
N-nitroso-levoleucovorin-1	Levoleucovorin	4	1500 ng/day
N-nitroso-levoleucovorin-2	Levoleucovorin	4	1500 ng/day
N-nitroso-levomefolic acid-1	Levomefolic Acid	4	1500 ng/day
N-nitroso-levomefolic acid-2	Levomefolic Acid	4	1500 ng/day
N-nitroso-lisinopril	Lisinopril	5	1500 ng/day
N-nitroso-lorcaserin	Lorcaserin	1	26.5 ng/day
N-nitroso-mecamylamine	Mecamylamine	5	1500 ng/day
N-nitroso-meclofenamic acid	Meclofenamic Acid	5	1500 ng/day
N-nitroso-mefloquine	Mefloquine	4	1500 ng/day
N-nitroso-meropenem	Meropenem	4	1500 ng/day
N-nitroso-desmethyl-methadone	Methadone	3	400 ng/day
N-nitroso-methamphetamine	Methamphetamine	3	400 ng/day
N-nitroso-desmethyl-methylene blue	Methylene Blue	2	100 ng/day
N-nitroso-metolazone	Metolazone	5	1500 ng/day
N-nitroso-metoprolol	Metoprolol	4	1500 ng/day
N-nitroso-desmethyl-mifepristone	Mifepristone	2	100 ng/day
N-nitroso-migalastat	Migalastat	4	1500 ng/day
N-nitroso-desmethyl-minocycline-1	Minocycline	2	100 ng/day
N-nitroso-desmethyl-minocycline-2	Minocycline	3	400 ng/day
N-nitroso-mirabegron	Mirabegron	3	400 ng/day
N-nitroso-mitoxantrone-1	Mitoxantrone	4	1500 ng/day
N-nitroso-mitoxantrone-2	Mitoxantrone	2	100 ng/day
N-nitroso-moexipril	Moexipril	5	1500 ng/day
N-nitroso-moxifloxacin	Moxifloxacin	4	1500 ng/day

N-nitroso-nadolol	Nadolol	5	1500 ng/day
N-nitroso-nebivolol	Nebivolol	4	1500 ng/day
N-nitroso-desmethyl-neratinib	Neratinib	2	100 ng/day
N-nitroso-neratinib	Neratinib	5	1500 ng/day
N-nitroso-nicardipine	Nicardipine	5	1500 ng/day
N-nitroso-nifedipine	Nifedipine	5	1500 ng/day
N-nitroso-nimodipine	Nimodipine	5	1500 ng/day
N-nitroso-nintedanib	Nintedanib	5	1500 ng/day
N-nitroso-nisoldipine	Nisoldipine	5	1500 ng/day
N-nitroso-desmethyl-nizatidine	Nizatidine	1	26.5 ng/day
N-nitroso-nizatidine-1	Nizatidine	2	100 ng/day
N-nitroso-nizatidine-2	Nizatidine	3	400 ng/day
N-nitroso-olanzapine	Olanzapine	5	1500 ng/day
N-nitroso-oliceridine	Oliceridine	1	26.5 ng/day
N-nitroso-olodaterol	Olodaterol	5	1500 ng/day
N-nitroso-desmethyl-olopatadine	Olopatadine	4	1500 ng/day
N-nitroso-desmethyl-omadacycline-1	Omacycline	2	100 ng/day
N-nitroso-desmethyl-omadacycline-2	Omacycline	3	400 ng/day
N-nitroso-omadacycline	Omacycline	1	26.5 ng/day
N-nitroso-oritavancin-1	Oritavancin	4	1500 ng/day
N-nitroso-oritavancin-2	Oritavancin	5	1500 ng/day
N-nitroso-desmethyl-orphenadrine	Orphenadrine	1	26.5 ng/day
N-nitroso-ozanimod	Ozanimod	3	400 ng/day
N-nitroso-ozenoxacin	Ozenoxacin	4	1500 ng/day
N-nitroso-desmethyl-padimate o	Padimate O	2	100 ng/day
N-nitroso-perindopril	Perindopril	5	1500 ng/day
N-nitroso-desmethyl-pheniramine	Pheniramine	1	26.5 ng/day
N-nitroso-phenylephrine	Phenylephrine	2	100 ng/day
N-nitroso-desmethyl-phenyltoloxamine	Phenyltoloxamine	1	26.5 ng/day
N-nitroso-pindolol	Pindolol	4	1500 ng/day
N-nitroso-plazomicin-1	Plazomicin	4	1500 ng/day
N-nitroso-plazomicin-2	Plazomicin	2	100 ng/day
N-nitroso-plerixafor-1	Plerixafor	2	100 ng/day
N-nitroso-plerixafor-2	Plerixafor	2	100 ng/day
N-nitroso-plerixafor-3	Plerixafor	2	100 ng/day
N-nitroso-polythiazide	Polythiazide	5	1500 ng/day
N-nitroso-pramipexole	Pramipexole	3	400 ng/day
N-nitroso-prilocaine	Prilocaine	4	1500 ng/day
N-nitroso-primaquine	Primaquine	5	1500 ng/day
N-nitroso-proline	Proline	4	1500 ng/day
N-nitroso-desmethyl-promethazine	Promethazine	3	400 ng/day
N-nitroso-propafenone	Propafenone	2	100 ng/day
N-nitroso-desmethyl-propoxyphene	Propoxyphene	1	26.5 ng/day
N-nitroso-propranolol	Propranolol	4	1500 ng/day
N-nitroso-propylhexedrine	Propylhexedrine	3	400 ng/day
N-nitroso-protriptyline	Protriptyline	1	26.5 ng/day
N-nitroso-pseudoephedrine	Pseudoephedrine	4	1500 ng/day
N-nitroso-desmethyl-pyrimilamine	Pyrimilamine	1	26.5 ng/day
N-nitroso-desmethyl-quinupristin	Quinupristin	2	100 ng/day
N-nitroso-racepinephrine	Racepinephrine	2	100 ng/day
N-nitroso-ramipril	Ramipril	5	1500 ng/day
N-nitroso-desmethyl-ranitidine	Ranitidine	1	26.5 ng/day
N-nitroso-ranitidine-1	Ranitidine	3	400 ng/day
N-nitroso-ranitidine-2	Ranitidine	2	100 ng/day
N-nitroso-rasagiline	Rasagiline	2	100 ng/day
N-nitroso-relebactam	Relebactam	3	400 ng/day
N-nitroso-rifabutin	Rifabutin	5	1500 ng/day
N-nitroso-rilpivirine-1	Rilpivirine	5	1500 ng/day
N-nitroso-rilpivirine-2	Rilpivirine	5	1500 ng/day
N-nitroso-risdiplam	Risdiplam	5	1500 ng/day
N-nitroso-desmethyl-rivastigmine	Rivastigmine	2	100 ng/day
N-nitroso-desmethyl-rizatriptan	Rizatriptan	1	26.5 ng/day
N-nitroso-rolapitant	Rolapitant	5	1500 ng/day
N-nitroso-safinamide	Safinamide	3	400 ng/day
N-nitroso-salmeterol	Salmeterol	3	400 ng/day
N-nitroso-sapropterin-1	Sapropterin	4	1500 ng/day
N-nitroso-sapropterin-2	Sapropterin	5	1500 ng/day
N-nitroso-desmethyl-sarecycline	Sarecycline	3	400 ng/day
N-nitroso-sertraline	Sertraline	2	100 ng/day
N-nitroso-silodosin	Silodosin	4	1500 ng/day
N-nitroso-sotalol	Sotalol	4	1500 ng/day

N-nitroso-desmethyl-spinosad factor a	Spinosad	2	100 ng/day
N-nitroso-desmethyl-spinosad factor d	Spinosad	2	100 ng/day
N-nitroso-streptomycin	Streptomycin	4	1500 ng/day
N-nitroso-desmethyl-sumatriptan	Sumatriptan	1	26.5 ng/day
N-nitroso-tafenoquine	Tafenoquine	5	1500 ng/day
N-nitroso-desmethyl-tamoxifen	Tamoxifen	1	26.5 ng/day
N-nitroso-tamsulosin	Tamsulosin	4	1500 ng/day
N-nitroso-desmethyl-tapentadol	Tapentadol	1	26.5 ng/day
N-nitroso-telavancin-1	Telavancin	3	400 ng/day
N-nitroso-telavancin-2	Telavancin	4	1500 ng/day
N-nitroso-telavancin-3	Telavancin	4	1500 ng/day
N-nitroso-telavancin-4	Telavancin	5	1500 ng/day
N-nitroso-desmethyl-telithromycin	Telithromycin	4	1500 ng/day
N-nitroso-terbutaline	Terbutaline	5	1500 ng/day
N-nitroso-desmethyl-tetracaine	Tetracaine	1	26.5 ng/day
N-nitroso-tetracaine	Tetracaine	3	400 ng/day
N-nitroso-desmethyl-tetracycline	Tetracycline	3	400 ng/day
N-nitroso-desmethyl-thonzylamine	Thonzylamine	1	26.5 ng/day
N-nitroso-ticagrelor	Ticagrelor	5	1500 ng/day
N-nitroso-desmethyl-tigecycline-1	Tigecycline	3	400 ng/day
N-nitroso-desmethyl-tigecycline-2	Tigecycline	2	100 ng/day
N-nitroso-tigecycline	Tigecycline	5	1500 ng/day
N-nitroso-timolol	Timolol	5	1500 ng/day
N-nitroso-tirofiban	Tirofiban	4	1500 ng/day
N-nitroso-torsemide	Torsemide	5	1500 ng/day
N-nitroso-desmethyl-tramadol	Tramadol	1	26.5 ng/day
N-nitroso-trandolapril	Trandolapril	5	1500 ng/day
N-nitroso-trientine	Trientine	1	26.5 ng/day
N-nitroso-desmethyl-trimethobenzamide	Trimethobenzamide	1	26.5 ng/day
N-nitroso-desmethyl-trimipramine	Trimipramine	1	26.5 ng/day
N-nitroso-desmethyl-ulipristal acetate	Ulipristal Acetate	2	100 ng/day
N-nitroso-vancomycin	Vancomycin	4	1500 ng/day
N-nitroso-desmethyl-venlafaxine	Venlafaxine	1	26.5 ng/day
N-nitroso-vibegron	Vibegron	5	1500 ng/day
N-nitroso-vilanterol	Vilanterol	3	400 ng/day
N-nitroso-vortioxetine	Vortioxetine	3	400 ng/day
N-nitroso-desmethyl-zolmitriptan	Zolmitriptan	1	26.5 ng/day